(2) Any device identification(s) and control number(s) used;
(3) The date of service;
(4) The individual(s) servicing the device;
(5) The service performed; and
(6) The test and inspection data.

Subpart O—Statistical Techniques

§ 820.250 Statistical techniques.

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

EFFECTIVE DATE NOTE: At 61 FR 52654, Oct. 7, 1996, part 820 was revised, effective June 1, 1997. For the convenience of the user, the superseded text is set forth as follows:

PART 820—GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES: GENERAL

Subpart A—General Provisions

Subpart B—Organization and Personnel

Subpart C—Buildings

Subpart D—Equipment

Subpart E—Control of Components

Subpart F—Production and Process Controls

Subpart G—Packaging and Labeling Control

Subpart H—Holding, Distribution, and Installation

Subpart I—Device Evaluation

Subpart J—Records

AUTHORITY: Secs. 501, 502, 515, 518, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360e, 360h, 360i, 360j, 371, 374).

SOURCE: 43 FR 31508, July 21, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 820.1 Scope.

The regulation set forth in this part describes current good manufacturing practices for methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of all finished devices intended for human use. The regulation is intended to assure that such devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act. Part 820 establishes